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INCORPORATED

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PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)
P: 920.469.9099 • F: 920.469.4418 (Phyto)

February 16, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

FEB 25 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Dietary supplement increases mental and physical energy and performance.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

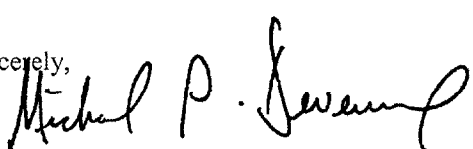
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/16/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Simple Energy with Rhodiola is a natural plant extract that increases the body's ability to cope with internal and external stress factors.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

2/16/05

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Sincerely,

Michael P. Devereux
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Clinically-studied Simple Energy with Rhodiola*: Enhances endurance*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Clinically-studied Simple Energy with Rhodiola*: Features 3% rosavins for increased energy*	Rhodiola (Rhodiola rosea) Root Extract

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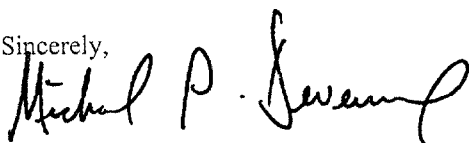
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

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Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Clinically-studied Simple Energy with Rhodiola*: Supports memory and mental clarity*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

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Title: Senior Vice President of Scientific Affairs

Date: _____

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Simple Energy with Rhodiola is a standardized extract of legendary Russian Rhodiola rosea root. It has been used for centuries to combat fatigue, increase physical strength and enhance mental stamina.*	Rhodiola (Rhodiola rosea) Root Extract

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By: 

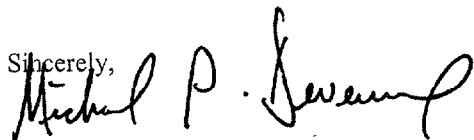
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/18/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	The standardized Rhodiola rosea root extract in this formula contains phytochemicals, rosavin and salidroside, that support mental and physical energy, support nervous system health, and promote mental well-being.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/18/05

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Michael P. Devereux
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Clinical studies have shown that Rhodiola rosea supports mental and physical energy, and promotes mental well-being.*	Rhodiola (Rhodiola rosea) Root Extract

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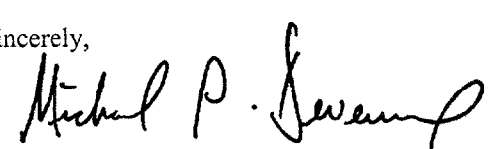
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February 19, 2005

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Simple Energy™* with Rhodiola	In a double-blinded crossover study, the effect of Rhodiola rosea extract on fatigue during night duty was investigated on 56 healthy physicians. The effect was measured using tests that gauged mental fatigue involving complex perception and cognitive functions. The parameters were tested before and after night duty. The authors of this study noted that significant improvements in perception and cognitive functions were observed in the group taking the Rhodiola rosea extract.* The results indicate that Rhodiola rosea extract can reduce general fatigue and increase mental and physical energy under stressful conditions.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

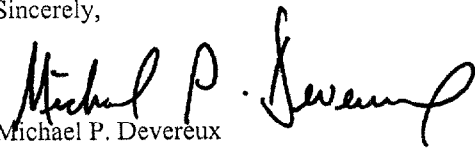
Title: Senior Vice President of Scientific Affairs

Date: _____

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Simple Energy™* with Rhodiola	Significant improvements in physical fitness, mental fatigue, and motor tests were observed in the group taking the Rhodiola rosea extract.* The results indicate that Rhodiola rosea extract can reduce general fatigue and increase mental and physical energy under stressful conditions.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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Simple Energy™* with Rhodiola	Laboratory studies have shown that Rhodiola rosea extract supports the balance of various neurotransmitters, such as norepinephrine, dopamine, and serotonin in the central nervous system.*	Rhodiola (Rhodiola rosea) Root Extract

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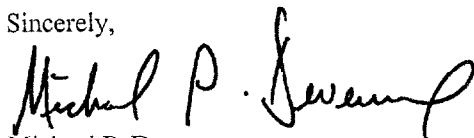
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Simple Energy™* with Rhodiola	In more than 250 clinical case studies, physicians reported that Rhodiola rosea extract helps support mental well-being in their patients.*	Rhodiola (Rhodiola rosea) Root Extract

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By: _____

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Tyler Encapsulations ♦ Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 ♦ F: 503.582.0467

**ENZYMATIC THERAPY™
&
PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

February 22, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Clinically-studied Simple Energy with Rhodiola has been shown to enhance the level of enzymes, RNA and proteins important to muscle recovery after exercise.* It also has been shown to support healthy levels of beta-endorphin in the blood plasma, which helps modulate the hormonal changes typical of stress.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

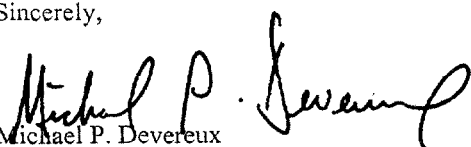
By: _____
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer



ENZYMATIC THERAPY INCORPORATED

What **Better** feels like.™

INTEGRATIVE THERAPEUTICS INC.™

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Simple Energy™* with Rhodiola	Simple Energy with Rhodiola contains the highest percent of the active component, Rosavins – for optimum energy.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

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Michael P. Devereux
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Energy™* with Rhodiola	Simple Energy with Rhodiola supports your cardiovascular system.*	Rhodiola (Rhodiola rosea) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

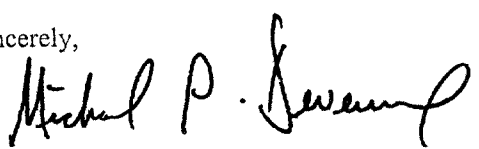
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